METHOD PERFORMANCE CHARACTERISTICS

The following is a summary of performance characteristics obtained from evaluations of the Technicon H•3 RTC/RTX reticulocyte method. The values shown in this section are point estimates of performance which can be expected from the method. Similar evaluations may produce slightly different results depending on the characteristics of the donor population.

ACCURACY

Reticulocyte Count

Accuracy of the Technicon H•3 RTC/RTX reticulocyte method was evaluated by comparison to the NCCLS[5] proposed standard for reticulocyte counting using new methylene blue. Fifty samples were obtained from apparently healthy donors and forty-eight samples were obtained from hospital patients including patients with known red cell abnormalities. Each sample was counted independently by two technologists using the NCCLS method and was assayed in duplicate on a Technicon H•3 for a total sample size of n = 196. Reference absolute counts were obtained from the technologist % reticulocyte result and an RBC count from a Technicon H•2 system. The test results appear in the table below.

Table 4-4 ACCURACY VERSUS MANUAL COUNTS

Parameter	r	Slope	Intercept	Syx	Reference Mean	H•3 Mean	Range of Samples
% retic	0.97	0.93	0.0	0.56	2.0	1.9	0.2 to 26.2
abs retic (10^9/L)	0.93	0.86	6.4	22.6	84.9	79.1	7.4 to 552.8

Due to the substantial error associated with the manual counting technique[6], laboratories performing similar accuracy evaluations may obtain incorrect least squares regression coefficients when the range of samples is small[7]. In this event, the coefficients can be corrected by averaging manual results from 4 or more technologists, or by calculating the regression coefficients using a method derived by Deming[8].

RBC Indices

Accuracy of the Technicon H•3 RTC/RTX reticulocyte method RBC indices was evaluated by comparison to the RBC indices obtained from the H•3 RBC/platelet and hemoglobin methods (CBC/Diff mode) in the experiment described above (n = 196). Accuracy of MCV, CHCM, RDW, and HDW was evaluated by comparison to the identical parameter obtained from the RBC/platelet method. The accuracy of CH was evaluated by comparison to MCH which is calculated from the RBC count and hemoglobin measurement.

Table 4-5 ACCURACY OF RBC INDICES

Parameter	r	Slope	Intercept	Syx	Mean in CBC/Diff Mode	Mean in Reticulocyte Mode	Bias
MCV	0.974	0.88	10.0	1.0	84.8	84.7	-0.1
CHCM	0.988	1.06	-1.6	0.7	33.1	33.5	0.4
CH	0.980	0.95	2.0	0.6	27.5	28.0	0.5
RDW	0.937	1.06	-0.8	0.5	15.7	15.8	0.1
HDW	0.990	1.13	-0.25	0.14	2.79	2.90	0.11

WITHIN RUN PRECISION CHARACTERISTICS

Within run precision of the reticulocyte method was tested by 25 replicate assays performed for each of 5 samples obtained from apparently healthy donors. The average result, which represents typical performance, appears in the table below.

Table 4-6 REPLICATE PRECISION

Parameter	Mean	SD	CV (%)
Retic (%)	1.1	0.14	12.7
Abs Retic (10^9 cells/L)	52.2	6.3	12.1
MCV (fL)	90.5	0.44	0.5
MCVr (fL)	110.8	2.1	1.9
CHCM (g/dL)	32.3	0.20	0.6
CHCMr (g/dL)	27.7	0.5	1.5
CH (pg)	28.6	0.08	0.3
CHr (pg)	29.9	0.5	1.3
RDW (%)	13.2	0.09	0.7
RDWr (%)	14.8	1.2	8.1
HDW (g/dL)	2.59	0.05	1.9
HDWr (g/dL)	3.04	0.22	7.2
HHDW (pg)	3.40	0.02	0.6
HHDWr (pg)	3.84	0.28	7.3

LINEARITY

The linearity of the % reticulocyte count was tested by making serial dilutions of a human pool prepared to obtain a high reticulocyte count. The results from this study indicate that the response is linear from 0% to 26% reticulocytes.

CARRYOVER

Carryover of the reticulocyte method was measured using high level and low level human pools. No detectable carryover was observed for reticulocyte counts.

PREPARED SAMPLE STABILITY

Reticulocyte Count

Prepared sample stability over the claimed range of 15 to 90 minutes was tested by assaying 15 prepared samples obtained from apparently healthy donors from 15 to 90 minutes at 15 minute intervals. The test results indicate that all samples were within ±0.5% of the % reticulocyte recovery obtained at 30 minutes.

RBC Indices

With the exception of CH and CHr, the RBC indices are not stable over the entire incubation period. When reporting results for RBC indices other than CH and CHr, the samples should incubate for at least 15 minutes, but not longer than 20 minutes. CH and CHr are stable over the entire 15 to 90 minute incubation period.